

## **REMARKS**

### **Initial Remarks**

Applicant thanks Examiner Houston for confirming with Applicant's representative, Mr. Jeremy Bond, on May 11, 2009, that the Office Action issued on March 12, 2009, was a non-final Action.

### **Interview Summary**

Applicant also thanks Examiner Houston for the courtesy of a telephonic interview with Applicant's representative, Mr. Jeremy Bond, on June 9, 2009. During the interview, Applicant's representative presented proposed claim language for claims 24, 31, and 52. In response, Examiner Houston indicated that she believed that the proposed language of claim 24 "did not seem to offer any novel features over other existing art." Interview Summary, p. 4. With respect to proposed claim 31, Examiner Houston indicated that further review of the prior art would be required to determine the interchangeability of the different stent types described by the Dua reference. *See id.* With respect to proposed claim 52, Examiner Houston indicated that a tip described by the Weaver reference would be "capable" of penetrating tissue if enough force was applied. *See id.*

### **Status of the Claims**

Claims 1-23 and 35-46 were previously cancelled. By this amendment, claims 24-29, 31, 33, 34, 47, 50, and 52-57 have been amended and claim 58 has been added. Claims 24-34 and 47-58 remain pending and under consideration.

Independent claim 24 has been amended to recite a distal tip having a proximal facing surface with an outer diameter, and an outer catheter having a distal end

selectively disposed against the proximal facing surface of the distal tip and an outer diameter substantially the same as the outer diameter of the distal tip. Support for this amendment can be found throughout the as filed specification and drawings, including for example, FIG. 5 and paragraphs 47, 48 of the corresponding published application (U.S. Patent Application Publication No. 2004/0098105). Claim 31 has been rewritten in independent form. Claims 25-29, 33, 34, 47, 50, and 52-57 have been amended to depend from independent claim 31. Claim 58 recites a self-expandable stent that is collapsible so that the stent can retract into the delivery system, support for which can be found in paragraph 49 and FIGs. 6(g-h) of the published application. Accordingly, no new matter has been added.

**35 U.S.C. § 103(a) Rejection**

The Office rejects claims 24-34 and 47-57 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,599,299 to Weaver et al. ("Weaver") in view of U.S. Patent Application Publication No. 2002/0032487 to Dua et al. ("Dua"). Office Action, p. 2. In particular, the Office alleges that Weaver discloses all the elements of claim 24 except for a stent that is "self-expanding with an outer catheter." *Id.* at p. 3. The Office also alleges that Dua discloses "a biliary stent that can either be non-expanding or self expanding," and that it would have been obvious "to incorporate a self-expanding biliary stent with the outer catheter in place of the stent disclosed by Weaver since Dua teaches that the two structures are equivalents known in the art." *Id.* at p. 3, 4.

Applicant respectfully disagrees with and traverses this rejection at least because Weaver and Dua, taken alone or in combination, fail to disclose, teach, or suggest, each and every limitation recited by amended independent claims 24 and 31. With regard to

amended claim 24, neither reference discloses, teaches, or suggests a stent delivery system having a distal tip with “a proximal facing surface having an outer diameter” and an outer catheter having “a distal end selectively disposed against the proximal facing surface of the distal tip” and having “an outer diameter substantially the same as the outer diameter of the distal tip.” In addition, one of ordinary skill in the art would not modify the Weaver delivery system to include Dua’s esophageal stent, so as to make amended claim 31 obvious. As discussed below, such a modification would destroy the purpose of the Weaver system.

Initially, the Office bears the burden of factually supporting any *prima facie* conclusion of obviousness. See M.P.E.P. § 2142. As articulated in *KSR Int’l Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (2007), the obviousness evaluation involves determining “whether there was an apparent reason to combine” the prior art elements relied upon to establish obviousness. *KSR*, 82 U.S.P.Q. 2d at 1369.

The Office alleges that Dua discloses “a biliary stent that can either be non-expanding or self expanding.” Office Action, p. 3. Applicant respectfully disagrees with this characterization of Dua.

Dua is directed to various prosthesis having sleeve valves. See Dua, Abstract. An anti-reflux prosthesis is designed for placement within the esophagus, as opposed to the biliary ducts, and includes “flared” self-expanding stents 20, 21. *Id.* at para. [0029], FIG. 1. Such flared stents are designed to maintain the position of the prosthesis within the esophagus. *Id.* at para. [0036], [0040], FIG. 5. Clearly Dua recognized that flared stents could be used in the esophagus, but did not envision using that type of stent within a biliary duct.

In marked contrast to esophageal stenting, and in a separate embodiment, Dua describes placing a “tubular drainage stent 60” within a bile duct, pancreatic duct, or urethra. *Id.* at para. [0046], [0048], FIGs. 11-14 (emphasis added). This type of “straight” tubular stent is “... typically non-expanding, unlike a [*sic*] the wire or open-frame stents of FIGS. 1-10.” *Id.* at para. [0046] (emphasis added). Thus, Dua expressly limits biliary stenting to the use of a straight stent, and teaches away from placing a flared stent (as shown in Figs. 1-7) within a biliary duct.

Likewise, Weaver does not use a flared stent in the biliary duct, but rather places a straight stent within a biliary duct. See Weaver, col. 12, ll. 15-53, FIGs. 17A-18. Specifically, Weaver describes the use of “a 10 French tubular stent.” *Id.* at col. 12, ll. 23-24 (emphasis added). Like Dua, Weaver describes only stenting the biliary duct with a straight non-expanding stent, and not a flared self-expanding stent.

Moreover, the use of a straight stent is consistent with the very purpose of Weaver, which is the cannulation of a biliary duct. See *id.* at col. 6, ll. 18-33. Such cannulation includes placing a stent around a biliary calculus or other obstruction. See *id.* at col. 10, ll. 15-21. Stenting around a biliary obstruction with a straight non-expanding stent provides the most rigid and reliable structure for permitting fluid flow within a biliary duct. Because different types of stents are used in different anatomical locations, one of ordinary skill, relying on Weaver and/or Dua, would have no reason to place a flared self-expanding stent in the biliary duct and therefore would not have modified the Weaver delivery system to include a flared self-expanding stent.

For at least the foregoing reasons, Applicant respectfully submits that pending claims 24-34 and 47-57 are distinguishable over the prior art and in condition for

allowance. Thus, Applicant respectfully requests that the Office withdraw the 35 U.S.C. § 103(a) rejection of these claims. Applicant also submits that new claim 58 is allowable at least due to its dependency from claim 31.

**Conclusion**

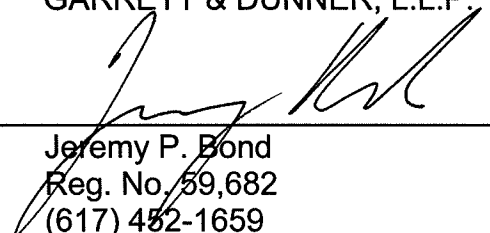
In view of the foregoing remarks, Applicant submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: July 13, 2009

By:   
Jeremy P. Bond  
Reg. No. 59,682  
(617) 452-1659